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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,843	03/31/2000	Barbara A. Gilcrest	06225.0003.CPUS02	2644

22930 7590 08/24/2005  
HOWREY LLP  
C/O IP DOCKETING DEPARTMENT  
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/540,843

Applicant(s)

GILCHREST ET AL.

Examiner

Brian Whiteman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 51, 52, 57, 58, 69, 85 and 89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/25/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims pending in the application are 1-11, 13-17, 19, 20, 23, 25, 26, 29, 32, 51, 52, 57, 58, 69, 71, 72, 75-79, 81-83, 85, 86, 88, 89, 93-95, 98-105 and 110-113.

Continuation of Disposition of Claims: Claims allowed are 1-11, 13-17, 19, 20, 23, 25, 26, 29, 32, 71, 72, 75-79, 81-83, 86, 88, 93-95, 98-105 and 110-113.

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## **DETAILED ACTION**

### **Non-Final Rejection**

Claims 1-11, 13-17, 19, 20, 23, 25, 26, 29, 32, 51, 52, 57, 58, 69, 71, 72, 75-79, 81-83, 85, 86, 88, 89, 93-95, 98-105, and 110-113 are pending.

Applicant's traversal filed on 6/30/05 is acknowledged and considered by the examiner.

The finality of the action is withdrawn because of the revival of a prior art rejection against claims 85 and 89.

The indicated allowability of claims 57, 58, 69, 85, and 89 is withdrawn in view of the newly discovered reference(s) to Beer-Romero et al. (US 5858987), Russell-Jones et al. (US 6103243), and Hartman et al. (US 5455029). Rejections based on the newly cited reference(s) follow.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 7/25/05 was filed after the mailing date of the final rejection on 5/10/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 85 and 89 are rejected under 35 U.S.C. 102(e) as being anticipated by Beer-Romero et al. (US 5858987, cited on a previous PTO-892). Beer-Romero teaches topical application to skin cells of a mammal an antisense for inhibiting proliferation of the skin cells in a mammal (columns 31-36). Beer-Romero teaches the limitation in instant claim 89 (columns 31-36).

Applicant's arguments filed 9/10/02 have been fully considered but they are not persuasive.

In response to applicant's argument that the claims have been amended to not encompass the method of Beer-Romero, as their method only employed single stranded oligonucleotide, the argument is not found persuasive because the term "deoxynucleotides" still reads on the antisense used by Beer-Romero et al.

The intended use (said composition is suitable for medicinal or cosmetic use) of the composition in claims 51 and 57 does not have patentable weight for prior art rejections. See MPEP 2111.02. An intended use does not provide a structural difference between the claimed invention and the prior art.

Claim 51 remains rejected under 35 U.S.C. 102(b) as being anticipated by Villeponteau et al. (5,583,016). The limitation “at least said oligonucleotide has an oligonucleotide sequence consisting of SEQ ID NO: 5” reads on an oligonucleotide comprising an oligonucleotide sequence consisting of SEQ ID NO: 5. Villeponteau teaches a composition comprising an oligonucleotide sequence consisting of CUAACCCUAAC (SEQ ID NO: 2), which is complementary to a telomeric sequence. The DNA sequence of SEQ ID NO: 2 is CTAACCCTAAC and the complementary sequence (telomeric sequence) is GATTGGGATTG. See columns 4-5. The telomeric DNA sequence is 100% identical in the 3’ to 5’ direction to SEQ ID NO: 5 of the instant application. Furthermore, the complement still reads on the claimed product since the sequence was cloned involving dsDNA that would contain the claimed product.

Villeponteau teaches producing the cDNA for the RNA sequence and reagents comprising the oligonucleotide (columns 4-5). In addition, the complementary DNA sequence taught by Villeponteau would anticipate the claimed oligonucleotides sequence having a phosphodiester backbone because a phosphodiester backbone is the natural backbone for an oligonucleotide sequence.

Applicant’s arguments filed 6/30/05 with respect to 102 rejection have been fully considered and are not found persuasive.

In response to the argument that the prior art does not teach the sequence in the 5’ to 3’ direction, the argument is not found persuasive because while it is acknowledged that MPEP 2429 (paragraph 17) requires applicants to submit oligonucleotide strands in 5’ to 3’ direction since only single strands may be depicted in the “sequence listing”, however, the language of the

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claim “has an oligonucleotide consisting of SEQ ID NO: 5” does not limit the oligonucleotide to only the 5’ to 3’ direction.

Claims 57, 58, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Russell-Jones et al. (US 6103243). The limitation “at least said oligonucleotide has an oligonucleotide sequence consisting of SEQ ID NO: 3” reads on an oligonucleotide comprising an oligonucleotide sequence consisting of SEQ ID NO: 3. Russell-Jones teaches a nucleotide sequence comprising SEQ ID NO: 3 of the instant invention (column 24). Russell-Jones teaches the limitation “comprises a 5’ phosphate” in instant claim 58 and 69 (column 24).

Claim 69 is rejected under 35 U.S.C. 102(e) as being anticipated by Hartman et al. (US 5455029). The limitation “at least said oligonucleotide has an oligonucleotide sequence consisting of SEQ ID NO: 1 or SEQ ID NO: 4” reads on an oligonucleotide comprising an oligonucleotide sequence consisting of SEQ ID NO: 1 or SEQ ID NO: 4. Hartman teaches a nucleotide sequence comprising SEQ ID NO: 1 or SEQ ID NO: 4 of the instant invention having a 5’ phosphate (columns 49-50 and figure 30).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51 and 52 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Villeponteau et al. (5,583,016) taken with Akhavan-Tafti (6,020,138).

Villeponteau teaches a composition comprising an oligonucleotide sequence consisting of CUAACCCUAAC (SEQ ID NO: 2), which is complementary to a telomeric sequence. The DNA sequence of SEQ ID NO: 2 is CTAACCCTAAC and the complementary sequence (telomeric sequence) is GATTGGGATTG. See columns 4-5. The telomeric DNA sequence is 100% identical in the 3' to 5' direction to SEQ ID NO: 5 of the instant application. Furthermore, Villeponteau teaches producing the cDNA for the RNA sequence and reagents comprising the



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oligonucleotide (columns 4-5). In addition, the complementary DNA sequence taught by Villeponteau would anticipate the claimed oligonucleotides sequence having a phosphodiester backbone because a phosphodiester backbone is the natural backbone for an oligonucleotide sequence. However, Villeponteau does not specifically teach the oligonucleotide comprising a 5' phosphate.

However, at the time the invention was made, Akhavan-Tafti teaches a method of synthesizing single or double stranded polynucleotides using an oligonucleotide having a 5' phosphate (abstract and columns 2-3). It has been discovered that a series of short oligonucleotide-5'-phosphates can be simultaneously ligated onto a template-bound primer in a contiguous manner to produce the complementary strand of a template polynucleotide or nucleic acid (column 3). Akhavan-Tafti teaches that the method is useful in a variety of applications, including cloning, preparing labeled polynucleotides for diagnostic use, mutation analysis and screening, gene expression monitoring and sequence analysis (abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Villeponteau and Akhavan-Tafti, namely to produce an oligonucleotide consisting of SEQ ID NO: 5 of the instant specification, wherein the oligonucleotide comprises a 5' phosphate. One of ordinary skill in the art would have been motivated to produce the oligonucleotide because Akhavan-Tafti teaches that an oligonucleotide having a 5' phosphate can be produced in a large quantity for use in a variety of applications.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 6/6/05 have been fully considered but they are not persuasive for the same reasons as set forth under the response to applicant's argument against the 102(b) rejection.

### *Conclusion*

Claims 1-11, 13-17, 19, 20, 23, 25, 26, 29, 32, 71, 72, 75-79, 81-83, 86, 88, 93-95, 98-105, and 110-113 are in condition for allowance because the claims are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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